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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,555	11/21/2003	Dennis George Anthony Nelson	020018-C2-03-DCL	3549
Pfizer Inc. 201 Tabor Road Morris Plains, NJ 07950			EXAMINER KRASS, FREDERICK F	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,555

Applicant(s)

ANTHONY NELSON ET AL.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,23,25,27,29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12,23,25,27,29 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2-4-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Claim Informalities

The following change is recommended to correct a minor oversight: Claim 23, second line, the word --- is --- should be inserted immediately after "source".

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 23, 25, 27, 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 12 and 25, the terms "high" alcohol/surfactant levels near the beginning of the claims, and "low" temperature stable and the terms "substantially" clear/free of impurities at the end of the claims, are relative terms which are inadequately defined by the specification to serve as definite limitations. (While the specification may provide examples of the values of such terms, it does not provide an adequate definition of the terms themselves).

2) Claims 12 and 25, the various percentage values recited therein are unclear in meaning because they do not include the basis for the measurement, e.g. percent by weight based on the total weight of the composition, percent by weight of the orally acceptable carrier, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite without knowing which method of measurement was used.)

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3) Claim 23 is incomplete insofar as it depends on a canceled claim.

4) Claim 25, fifth and sixth lines, the claim is incomplete and confusing; apparently the phrase "cyclodextrin selected from the group consisting of" was inadvertently omitted, and should be inserted immediately after the word "said" at the end of the fifth line.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 23, 25, 27, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimada et al (USP 5,626,837).

The prior art discloses oral compositions which contain 0.005 to 0.2 percent cationic bactericide (col. 2, lines 44-50) and 0.01 to 10 percent cyclodextrin (col. 3, lines 39-48). They also contain fluoride ion sources in amounts sufficient to provide 250ppm to 1500ppm, i.e. standard anticaries fluoridating agents such as sodium fluoride and stannous fluoride. See specifically working examples 6 and 7 at col. 12. Note the use of the cationic bactericide triclosan in working example 6. These compositions are stable during storage (col. 1, line 62), which would inherently encompass low temperatures, e.g. during refrigerated shipping, and are clear (see the working examples, which use the legend provided at col. 6, lines 47-53), and thus free of precipitants, flocculants and crystals, which would cause turbidity. Furthermore, since the same cyclodextrins

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are being used in substantially the same percentages by the prior art as by Applicant, the prior art cyclodextrins will inherently be "capable of solubilizing" triclosan without the use of high alcohol levels, high surfactant levels, or other phenolic cosolvents. The treatment of gingivitis and plaque is plainly implicit in the prior art disclosure, given its disclosure of known anti-gingivitis and antiplaque agents, e.g. cetylpyridinium chloride, and their incorporation into conventional oral care compositions commonly used for treating plaque. (Alternatively, the use of such compositions as taught by the prior art for oral hygiene would inherently result in the retarding/treatment of plaque and gingivitis, which are present to some extent in all adults).

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 23, 25, 27, 29 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,245,321.

The instant and conflicting claims are clearly drawn to overlapping subject matter, the differences between them being of a minor nature only. Specifically, the conflicting claims recite dentrifices in the form of a clear tooth gel, whereas the instant claims are broader, permitting either a toothpaste or a "substantially clear" tooth gel. The selection of a tooth gel from the instant claims is self-evident given their construction, and it would have been equally self-evident to have selected the subset of "clear" tooth gels (as required by the conflicting claims) from the broader subset of "substantially clear" tooth gels claimed by the instant application.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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